

NOV 24 2004

## SECTION 5. SUMMARY AND CERTIFICATION

### A. DEVICE SUMMARY

#### Summary of Safety and Effectiveness

The following information constitutes the summary for the Commander II.

SUBMITTERS NAME: Cardiocom, LLC.  
ADDRESS: 1260 Park Road, Chanhassen, Minnesota 55317  
CONTACT PERSON: Constance G. Bundy  
TELEPHONE NUMBER: (763) 574-1976  
FAX NUMBER: 763-571-2437  
DATE OF SUBMISSION: Prepared October 15th, 2004

**1. Identification of device**

Proprietary Name: Commander II

Common Name: Noninvasive blood pressure measurement system

Classification Status: Class II per regulations 870.1130

Product Code: DXN

**2. Description of the Device**

The Commander II is an automated device that connects to the user's telephone system at home. It has a display that asks the user health related questions and has inputs for devices such as weight scales, blood pressure meters, and other vital sign measurement devices.

**3. Intended use**

The Commander II device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.

**4. Technological characteristics, comparison to predicate device.**

The Commander II is substantially equivalent to: Home Care Monitoring System, AvidCare Corp., K010029. The Commander II device and its predicate system have the same general use to provide the capability for health care professionals to monitor the vitals signs of their patients from remote locations.

**5. Discussion of functional and safety testing.**

The device has been tested according to the following standards:

- |                            |  |
|----------------------------|--|
| • EN60601-1-2, 2001        | EMC Emissions<br>EMC Immunity                                |
| • EN61000-3-2              | Limits for Harmonic Current Emissions                        |
| • FCC Part 68              | Connection of Terminal Equipment to the<br>Telephone Network |
| • UL and C-UL Listing Mark | UL Safety Standards  |

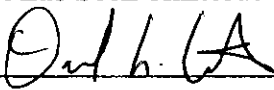
Verification and validation testing was conducted to establish performance and reliability characteristics of the device.

**6. Conclusion**

Based on the low risk device type, internal and external performance testing, it is Cardiocom's conclusion that Commander II presents no significant concerns about safety and effectiveness.

***B. TRUTH AND ACCURACY CERTIFICATION***

I certify that, in my capacity as President, I believe, to the best of my knowledge, that all data and information maintained on file are truthful and accurate, and that no material fact has been omitted.

 10/15/4

Daniel L. Cosentino, MBA  
President



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 24 2004

Cardiocom  
c/o Mr. Pedro E. Gonzales  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 55313

Re: K043096

Trade Name: Commander II  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: II (two)  
Product Code: DXN  
Dated: November 03, 2004  
Received: November 09, 2004

Dear Mr. Gonzales:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

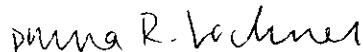
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**B. INDICATIONS FOR USE**510(k) Number K043096

Device Name: Commander II

**Indications for Use:**

The Commander II device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.

**Contraindications, Precautions and Warnings:**

The Commander II device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted. The Commander II is not intended as a substitute for medical care.

Prescription Use X OR Over the Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(Please do not write below this line – continue on another page if needed)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vachner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) number K043096